

DOK EXTRA STRENGTH STOOL SOFTENER- docusate sodium capsule, liquid filled
Liberty Pharmaceuticals, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient (in each softgel)

Docusate Sodium 250mg

Purpose

Stool softener

Uses

- for the prevention of dry, hard stools
- for relief of occasional constipation.
- this product generally produces a bowel movement within 12 to 72 hours.

Warnings - Do not use

- if you are taking mineral oil, unless directed by a doctor
- when abdominal pain, nausea, or vomiting are present
- for more than 1 week, unless directed by a doctor

Ask a doctor before use if

you notice a sudden change in bowel habits that persists over a period of 2 weeks

Stop use and ask a doctor if

- you have rectal bleeding
- you fail to have a bowel movement after use

If pregnant or breastfeeding

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **adults and children over 12 years of age and over:** take 1 softgel daily or as directed by a doctor
- **children under 12 years of age:** take as directed by a doctor

Other information

- **each softgel contains** sodium 15mg
- store at controlled room temperature 15° - 30° C (59°- 86° F)
- do not use if imprinted safety seal under cap is broken or missing

Inactive Ingredients

edible white ink, FD&C Red No# 40, FD&C Yellow No. 6, gelatin, glycerin, polyethylene glycol, propylene glycol, purified wter, sorbitol special.

Questions or comments?

Adverse Drug Event Call: **(800) 616-2471**

Product Labeling

MAJOR DOK™

Docusate Sodium 250 mg

Extra Strength Stool Softener

For use as a Stool Softener in treating & Avoiding Constipation

Distributed by:

Major Pharmaceuticals

31778 Enterprise Drive

Livonia, MI 48150, USA

Repackaged By :

Aidarex Pharmaceuticals LLC,

Corona, CA 92880

RX ONLY	LIBERTY Pharmaceuticals Inc.	PACKAGED BY: AIDAREX PHARMACEUTICALS LLC CORONA, CA 92880
	NDC: 00440-1466-30	
	DOCUSATE SODIUM	
	GENERIC FOR BRAND NAME: COLACE	
	250mg	30 CAPS
	EACH CAPSULE CONTAINS THE FOLLOWING ACTIVE INGREDIENTS	DOCUSATE SODIUM 250 MG EXTRA STRENGTH
	MFG: FOR: MAJOR PHARMACEUTICALS LIVONIA, MI 48150	
		DOCTOR _____ DATE _____
		PATIENT: _____
		RED OBLONG CAPSULE W/P20 ON ONE SIDE
		Take _____ Cap(s) Every _____ Hour(s)
		_____ Time(s) a day
		CAUTION: KEEP OUT OF REACH OF CHILDREN. STORE AT CONTROLLED ROOM TEMPERATURE 15-30 C (59-86) F

DOK EXTRA STRENGTH STOOL SOFTENER

docusate sodium capsule, liquid filled

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:0440-1466(NDC:0904-7891)

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	250 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	ORANGE (orange)	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	P20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0440-1466-30	30 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part334	08/27/2002	

Labeler - Liberty Pharmaceuticals, Inc. (012568840)

Revised: 9/2013

Liberty Pharmaceuticals, Inc.